

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

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Certifier LINDSEY

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200-272 for NOROMECTIN (ivermectin) Pour On for Cattle. The application provides for topical use of 0.5 percent ivermectin solution on cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, horn flies, lice, and mites. Norbrook Laboratories, Ltd.'s NOROMECTIN Pour-On for Cattle is approved as a generic copy of Merial Ltd.'s IVOMEK Pour-On for Cattle, approved under NADA 140-841. The application is approved as of

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200-272

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September 13, 2004, and the regulations are amended in 21 CFR 524.1193 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1193 [Amended]

■ 2. Section 524.1193 is amended in paragraph (b)(2) by adding in numerical order "055529".

Dated: October 8, 2004
October 8, 2004.

Steven D. Vaughn ovm

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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